



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94139d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 3003376941

July 14, 2003

Steven L. Carlson, D.V.M.
Owner, Central Valley Large Animal
1416A Road 72
Tipton, CA 93272

WARNING LETTER

Dear Dr. Carlson:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from [REDACTED], which was being treated for lameness. An investigation of your veterinary medical practice on March 20 and 21, 2003, at Tipton, California, and at [REDACTED] California, by the FDA revealed serious deviations of Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530). Such deviations cause veterinary drugs prescribed by you to be adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigators found that you have been verbally instructing [REDACTED] to administer 50-60cc of penicillin of the treatment of cattle for lameness, which is not in conformance with the approved labeling. The extralabel use of penicillin in dairy cows may only be done in compliance with 21 CFR Part 530, Extralabel Drug Use in Animals. These regulations require, among other conditions, that:

1. Prior to prescribing or dispensing an approved new animal drug for an extralabel use in food animals, the veterinarian must:
 - Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information.
 - Institute procedures to assure that the identity of the treated animal or animals is carefully maintained.
 - Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subject to extralabel treatment.

2. The new animal drug prescribed or dispensed for extralabel use must bear or be accompanied by labeling information which is adequate to assure the safe and proper use of the product. At a minimum, the following label information is required:
- The name and address of the prescribing veterinarian.
 - The established name of the drug (active ingredient), or if formulated from more than one ingredient, the established name of each ingredient.
 - Any directions for use specified by the veterinarian (including the class/species or identification of the animal or group of animals; and the dosage, frequency, route of administration, and duration of therapy).
 - Any caution statements.
 - The veterinarian's specified withdrawal/discard time(s) for meat, milk, eggs, or any other food which might be derived from the treated animal(s).

We request that you take prompt action to ensure that when you prescribe new animal drugs for extralabel use, you do so in accordance with the above requirements, and any other applicable requirements of 21 CFR Part 530.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Lawton W. Lum, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,



Dennis K. Linsley
District Director
San Francisco District